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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/660,763      | 09/12/2003  | Weiniu Gan           | CL001183DIVII       | 7422             |

25748 7590 09/08/2004

CELERA GENOMICS CORP.  
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 ROCKVILLE, MD 20850

EXAMINER

MONSHIPOURI, MARYAM

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                                   |  |
|------------------------------|---------------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/660,763  | <b>Applicant(s)</b><br>GAN ET AL. |  |
|                              | <b>Examiner</b><br>Maryam Monshipouri | <b>Art Unit</b><br>1652           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2 and 20-21, drawn to isolated kinases, classified in class 435, subclass 194.
- II. Claims 3 and 12, drawn to antibodies which specifically bind said kinases and methods of detecting said kinases using antibodies, classified in class 435, subclass 7.1.
- III. Claims 4-6, 8-11 and 22-23, drawn to isolated DNA sequences encoding said kinases, gene chips comprising said sequences, methods of producing said kinases, classified in class 435, subclass 194.
- IV. Claim 7, drawn to a transgenic non-human animal comprising said DNA sequences , classified in class 800, subclass 8.
- V. Claim 13, drawn to methods of detecting the presence of nucleic acids in a sample comprising contacting the sample with DNA sequences encoding said kinases (probes) that hybridize said nucleic acids, classified in class 435, subclass 6.
- VI. Claims 14-16 and 19, drawn to methods of identifying modulators or agents that bind said kinases, classified in class 435, subclass 15.
- VII. Claim 17, drawn to a pharmaceutical composition comprising modulators or agents that bind said kinases, classified in class 514, subclass 789.
- VIII. Claim 18, drawn to methods of treatment comprising administering modulators of said kinases, classified in class 424, subclass 94.1.

The inventions are distinct, each from the other because of the following reasons:

The peptides of Group I, the antibodies of Group II, the DNA of Group III, the transgenic animal of Group IV, the modulator composition of Group VII are each patentably distinct from the other. This is because each product has an unrelated chemical structure and function.

The peptides of Group I, the antibodies of Group II, the transgenic animal of Group IV and the composition of Group VII are each patentably distinct from the hybridization assay method of Group V because said products are neither made nor used by said method.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case The DNA of Group III may be used for recombinant expression of said kinases which is a totally different method than the of Group IV.

The DNA of Group III is unrelated to the method of Group VIII because said product is neither made nor used by said method.

Inventions I and VI or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case the peptides of Group I may be used for antibody preparation which is a totally different method than those of Groups VI or VIII.

The peptides of Group I are unrelated to the method of Group V because said product is neither made nor used by said method.

The antibodies of Group III, the transgenic animal of Group IV, and the composition of Group VII are each patentably distinct from any of the methods of Group V, VI and VIII because said products are neither made nor used by any of said methods.

The methods of Group V, VI and VIII are each patentably distinct from the other because each method has different steps and different end-points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an asserted product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to

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maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Maryam Monshipouri Ph.D.  
Primary Examiner

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